IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVENTIS PHARMA S.A., SANOFI-AVENTIS U.S., LLC, Plaintiffs, v. HOSPIRA, INC., APOTEX INC. and APOTEX CORP., Defendants.	Civil Action No. 07-721 (GMS) (Consolidated)

APOTEX'S MOTION *IN LIMINE* TO EXCLUDE TESTIMONY OF DR. ERIC KALER REGARDING CHEMICAL STABILITY ("APOTEX MIL #1")

SUBJECT TO PROTECTIVE ORDER – REDACTED

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Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex") move the Court *in limine* to exclude any testimony by Plaintiffs' expert witness Dr. Eric Kaler relating to chemical stability of the asserted claimed inventions or of the accused formulation because Dr. Kaler did not opine on chemical stability in any of his expert reports and was unable or unwilling to answer questions posed to him regarding chemical stability during his deposition.

FACTUAL BACKGROUND

In its claim construction order, the Court construed the term "consisting essentially of" in claims 2, 5, and 10 of the '561 Patent to mean "composed of the listed ingredients, and may include other ingredients that do not affect the basic and novel properties of the invention." (Doc. No. 153 at 2-3 & n.7 (citing *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351,1354 (Fed. Cir. 1998)).) In view of this construction, the issue of what precisely are the "basic and novel properties" of the claimed subject matter is important to issues of non-infringement. Specifically, whether a particular ingredient not listed in claims 2, 5, and 10 of the '561 Patent, such as [redacted] affects the basic and novel properties of the claimed subject matter directly impacts the infringement inquiry in this case.

Certain of the parties' expert witnesses have, in their expert reports and at their depositions, opined on what constitute the "basic and novel properties" of the subject matter of claims 2, 5, and 10 of the '561 Patent. [redacted]

[redacted]

[redacted]

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1 [redacted]

[redacted] Because Dr. Kaler did not opine in is opening expert report, in his rebuttal expert report, or in his deposition on whether chemical stability is a basic and novel property of the formulations recited in claims 2, 5 and 10 of the '561 Patent, he should not be permitted to offer testimony on this issue at trial.

ARGUMENT

Because Dr. Kaler did not opine on whether chemical stability is a basic and novel property of the formulations recited in claims 2, 5, and 10 of the '561 Patent, he should be precluded from providing expert testimony on this issue at trial. Discovery rules governing disclosure of expert testimony provide that such disclosure must be accompanied by a written report that must contain "a complete statement of all opinions the witness will express and the basis and reasons them." Fed. R. Civ. P. 26(a)(2)(B) (emphasis added). The consequences for a party's failure to comply with Rule 26(a)(2)(B) are governed by Rule 37(c)(1). Under Rule 37(c)(1), a party that without substantial justification fails to disclose information required by Rule 26(a) is not, unless such failure is harmless, permitted to use as evidence at a trial, at a hearing, or on a motion any witness or information not so disclosed. *See* Fed. R. Civ. P.

37(c)(1); *see also In re Safeguard Scientifics*, Civ. No. 01-3208, 2004 U.S. Dist. LEXIS 23494, at *5-6 (E.D. Pa. Nov. 17, 2004) ("[I]f an expert's initial report does not include a complete statement of opinions to be expressed and the basis for these opinions, a court may prohibit the expert from later testifying on issues or opinions not addressed in the initial report."); *Salgado v. General Motors Corp.*, 150 F.3d 735, 742 (7th Cir. 1998) ("[T]he sanction of exclusion is automatic and mandatory unless the sanctioned party can show that its violation of Rule 26(a) was either justified or harmless.").

Dr. Kaler has had ample opportunity to offer his opinion on the issue, addressed by Defendants' experts, that chemical stability is a "basic and novel property" of the claimed formulations. Dr. Kaler could have opined on this issue in his opening expert report, in a supplemental report, or in his rebuttal expert report. He did not. Further, when directly asked about whether he had an opinion about this issue at his deposition, Dr. Kaler refused to provide a direct, coherent answer. (*See* Ex. H at 28:17-30:25; *id.* at 31:5-15 [redacted] ; *id.* at 31:16-38:7.)

To allow Dr. Kaler to offer testimony on this issue at trial after declining several opportunities to do so during the discovery process should not be permitted under the Federal Rules of Civil Procedure. *See Cooper v. Southern Co.*, 390 F.3d 695, 728 (11th Cir. 2004) ("Because the expert witness discovery rules are designed to allow both sides in a case to prepare their cases adequately and to prevent surprise, compliance with the requirements of Rule 26 is not merely aspirational.") (internal citations omitted); *see also Flynn v. Langfitt*, Civ. A. No. 88-3551, 1991 WL 24956, *3 (E.D. Pa. Feb. 26, 1991) (granting defendant's motion to preclude the

plaintiffs from introducing expert testimony which exceeds the scope of the opinions contained in plaintiffs' expert's report). Accordingly, the Court should preclude such testimony at trial.

CONCLUSION

Apotex respectfully requests that the Court grant its motion and enter an order excluding any testimony proffered by Dr. Kaler at trial regarding whether chemical stability is a "basic and novel property" of the formulations recited in claims 2, 5, and 10 of the '561 Patent.

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EXHIBITS A THROUGH D

REDACTED

EXHIBIT E

prosecution history confirms that this is a novel advance over the prior art: "[i]t has been discovered that, by the use of the pharmaceutical dosage forms of the present invention, it is possible to greatly reduce the ethanol concentrations used". (JA1315).

Second, by eliminating Cremophor and substantially reducing the amount of ethanol in the perfusion, the invention reduces the incidence of alcohol intoxication and anaphylactic manifestations that often resulted from prior art formulations. (*See* '561 patent at 2:48-51 (JA0034) ("[t]he anaphylactic shock phenomena which were observed with the solutions of the prior art are not observed with these solutions"). Again, the applicants noted this novel advance over the prior art during prosecution. (JA1317 ("the perfusion of the present invention contains ethanol in the amount of about one order of magnitude less than the systems of *Tarr* et al. . . . A very important advantage of having less ethanol in the perfusion is the resultant reduction of alcohol intoxication during treatment")).

Third, the claimed formulations allow for a more physically and chemically stable perfusion than the prior art, even with the increase in the concentration of active principle. As stated by the specification, stable perfusions according to the prior art were only possible at a lower concentration of the active principle. (*See* '561 patent at 1:49-53 (JA0034) ("To obtain a mixture which is stable from both a physical standpoint and a chemical standpoint, the authors of [a prior art reference] state that it is necessary to limit the concentration of active principle in the perfusion solution. . .")). Before the PTO, the applicants also stated that "[t]he solution [disclosed in the prior art] is much less stable as an injectable solution than that of the present invention, and would not be recommended for commercial use in injectable solutions". (JA1429).

In sum, the intrinsic evidence defines the "basic and novel properties" achieved by the invention disclosed in the '561 patent; namely, an increased concentration of active ingredient; a reduction of potentially harmful excipients and corresponding reduction of side-effects; and adequate stability at these higher concentrations. Based on settled law interpreting the phrase "consisting essentially of", then, only the addition of substances that materially affect the stability of such highly concentrated formulations containing the specified excipients are excluded from the relevant claims.

The prosecution history illuminates and defines how the term is to be applied in the context of the patented invention. That the phrase "consisting essentially of" should be understood to exclude only the addition of surfactants such as pluronic L64 that impairs the stability of the solution is demonstrated by the Notice of Allowability for the '561 patent: "[a]pplicants' remarks that the tests performed as set forth . . . that the presence of pluronic L64 would materially affect the basic and novel characteristics of the claimed composition and thus is excluded from the scope of the present claim. **Therefore, carriers having similar characteristics as pluronic L64 are excluded from the claims.**" (JA1435 (emphasis added)).

This PTO statement was made in direct response to arguments made, and testing performed, by the '561 patent applicants. In response to an Examiner's rejection, applicants amended the pending claims of the '561 patent's parent application in September 1994 to read "consisting essentially of" instead of the open-ended phrase "comprising." (JA1313.) As part of this amendment, the applicants stated that the use of a sole surfactant (instead of the two-surfactant system disclosed in the *Tarr* reference) led to a "dramatic decrease" in the ethanol content of the formulation:

EXHIBITS F THROUGH H

REDACTED

CERTIFICATE OF SERVICE

I hereby certify that on September 8, 2009, I caused copies of the foregoing document to be served upon the following in the manner indicated:

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